UNITED STATES BANKRUPTCY COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

In re:	
23andMe HOLDING CO., et al.,[1]	**Case No. 25-40976 (BCW)**
Debtors	Chapter 11
	(Jointly Administered)
	Hearing Date: June 18, 2025
	Hearing Time: 9:00 AM CT
	Hearing Location:
	Thomas F. Eagleton US Courthouse
	111 S. 10th Street
	Courtroom 5 North
	St. Louis, MO 63102
	Related to Docket Nos.
	30, 125, 420, 693, 739, & 746

COMMONWEALTH OF KENTUCKY'S SUPPLEMENTAL OBJECTION TO THE DEBTORS' MOTION APPROVING SALE OF ASSETS (Relates to Docket Nos. 30, 125 & 420

Comes now the Commonwealth of Kentucky, by and through the Office of the Kentucky Attorney General, and files this Supplemental Objection to Debtors' Motion Approving the Sale of Assets. The objection joined by Kentucky (DE 687) is incorporated by reference.

1. The Debtors have conducted a second auction and chosen TTAM as the winning bidder. (DE 739). In addition to being a new winning bidder, TTAM's tendered Asset Purchase Agreement contains several significant changes from that of Regeneron, the first auction's winning bidder.

2. Among the most significant changes is that the Debtors and TTAM have chosen to achieve the purchase of Debtors assets through an equity transaction. (DE 746).

3. Like many other states, Kentucky does not oppose a sale on general principle, it does oppose the transfer of Kentucky consumers' genetic data without the express consent of those consumers, regardless of the underlying financial structure of the sale. This express consent requirement is not subsumed or modified by Debtors' various terms contained in their multiple versions of their privacy policies.

4. Kentucky law regulates direct-to-consumer genetic testing companies, such as the Debtors and TTAM. *See* Kentucky Revised Statute (KRS) 311.705(1)(c).[1]

5. This statute requires companies such as the Debtors and TTAM to obtain "[s]eparate express consent for transferring or disclosing the consumer's genetic data to any person other than the company's vendors and service providers, or for using genetic data beyond the primary purpose of the genetic testing product or service and inherent contextual uses." *See* KRS 311.705(2)(b)(2).

6. "Express consent" is defined by Kentucky law to mean "…a consumer's affirmative response, or the affirmative response of a consumer's legal guardian, attorney-in-fact, health care surrogate, or authorized representative, to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose." *See* KRS 311.705(1)(d).

7. The Office of the Kentucky Attorney General is authorized to "…bring an action in the name of the Commonwealth, or as parens patriae on behalf of consumers, to enforce this section." *See* KRS 311.705(4). This section also allows for the recovery of civil penalties, actual damages incurred by consumers, and the costs and expenses of

[1] This statute is attached hereto as Exhibit A.

litigation.

8. Like several other states, Kentucky's law does not provide for exceptions to this affirmative consent requirement for affiliates or other such entities. The only exceptions allowed under Kentucky law are for transfers to a company's vendors or service providers. See KRS 311.705(2)(b)(2).

9. TTAM cannot reasonably be considered to qualify as a vendor or service provider of the Debtors and thus must comply with Kentucky law and obtain express consent before taking possession or control of Kentuckians' genetic data.

10. As noted by others states in this case,[2] allowing the transfer of genetic data under the terms proposed by the Debtors and TTAM would violate Kentucky law. Absent specific provisions meant to comply with Kentucky law, the Debtors should not be permitted to transfer the genetic data of any Kentuckian without first obtaining express consent.

11. For the reasons stated above, any order permitting the sale of assets or equity to TTAM should include clear direction to the Parties that express consent must be obtained from every Kentuckian before any genetic data is transferred.

12. This objection and supplemental filing apply to both the winning bid and the backup bid by Regeneron, and the express consent requirement should apply to both, regardless of the nature of the sale.

13. Kentucky reserves the right to supplement or amend its Objection.

[2] See, e.g., Tennessee's supplemental objection, filed as DE 787.

WHEREFORE, Kentucky asks this Court to include in any order approving a sale the following:

1. A requirement that express consent be obtained from any Kentucky consumer regarding the sale, transfer, or change in the manner of use of that consumer's genetic data; and

2. The removal of any reference to governmental entities in the definition of persons in an APA.

Dated: June 17, 2025.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2025 a true and correct copy of the foregoing document is served via CM/ECF to all parties registered to receive such notice.

/s/ Christopher D. Hunt
Christopher D. Hunt

[1] A complete list of each of the Debtors in these chapter 11 cases may be obtained on the website of the Debtors' proposed claims and noticing agent at https://restructuring.ra.kroll.com/23andMe. The Debtors' service address for purposes of these chapter 11 cases is: 870 Market Street, Room 415, San Francisco, CA 94102.

EXHIBIT A

311.705 Genetic testing -- Guidelines for collection and use of genetic data.

(1) As used in this section:

(a) "Biological sample" means any material part of the human, discharge therefrom, or derivative thereof, such as tissue, blood, urine, or saliva, known to contain deoxyribonucleic acid (DNA);

(b) "Consumer" means an individual who is a resident of the state;

(c) 1. "Direct-to-consumer genetic testing company" means an entity that:

a. Offers genetic testing products or services directly to a consumer; or

b. Collects, uses, or analyzes genetic data that resulted from a direct-to-consumer genetic testing product or service and was provided to the company by a consumer.

2. "Direct-to-consumer genetic testing company" does not include any entity only when they are engaged in collecting, using, or analyzing genetic data or biological samples in the context of research, as defined in 45 C.F.R. sec. 164.501, conducted in accordance with the Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46, the Good Clinical Practice Guideline issued by the International Council for Harmonisation, or the United States Food and Drug Administration Policy for the Protection of Human Subjects under 21 C.F.R. pts. 50 and 56;

(d) "Express consent" means a consumer's affirmative response, or the affirmative response of a consumer's legal guardian, attorney-in-fact, health care surrogate, or authorized representative, to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic data for a specific purpose;

(e) 1. "Genetic data" means any data, regardless of its format, that concerns a consumer's genetic characteristics and includes but is not limited to:

a. Raw sequence data that result from a sequencing of a consumer's complete extracted or a portion of the extracted DNA;

b. Genotypic and phenotypic information that results from analyzing the raw sequence data; and

c. Self-reported health information that a consumer submits to a company regarding the consumer's health conditions and that is used for scientific research or product development and analyzed in connection with the consumer's raw sequence data.

2. "Genetic data" does not include de-identified data;

(f) "Genetic testing" means any laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; and

(g) "Person" has the same meaning as KRS 446.010.

(2) To safeguard the privacy, confidentiality, security, and integrity of a consumer's

genetic data, a direct-to-consumer genetic testing company shall:

(a) Provide clear and complete information regarding the company's policies and procedures for collection, use, or disclosure of genetic data by making available to a consumer:

1. A high-level privacy policy overview that includes basic, essential information about the company's collection, use, or disclosure of genetic data; and

2. A prominent, publicly available privacy notice that includes, at a minimum, information about the company's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices;

(b) Obtain a consumer's consent for collection, use, or disclosure of the consumer's genetic data including, at a minimum:

1. Initial express consent that clearly describes the uses of the genetic data collected through the genetic testing product or service, and specifies who has access to test results and how the genetic data may be shared;

2. Separate express consent for transferring or disclosing the consumer's genetic data to any person other than the company's vendors and service providers, or for using genetic data beyond the primary purpose of the genetic testing product or service and inherent contextual uses;

3. Separate express consent for the retention of any biological sample provided by the consumer following completion of the initial testing service requested by the consumer;

4. Informed consent in compliance with the Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46, for transfer or disclosure of the consumer's genetic data to third party persons for research purposes or research conducted under the control of the company for the purpose of publication or generalizable knowledge; and

5. a. Express consent for marketing to a consumer based on the consumer's genetic data; or for marketing by a third party person to a consumer based on the consumer having ordered or purchased a genetic testing product or service.

b. Marketing does not include the provision of customized content or offers on the Web sites or through the applications or services provided by the direct-to-consumer genetic testing company with the first-party relationship to the customer;

(c) Require valid legal process for disclosing genetic data to law enforcement or any other government agency without a consumer's express written consent;

(d) Develop, implement, and maintain a comprehensive security program to protect a consumer's genetic data against unauthorized access, use, or disclosure; and

(e) Provide a process for a consumer to:

1. Access the consumer's genetic data;
2. Delete the consumer's account and genetic data; and
3. Request and obtain the destruction of the consumer's biological sample.

(3) Notwithstanding any other provisions in this section, a direct-to-consumer genetic testing company may not disclose a consumer's genetic data to any entity offering health insurance, life insurance, or long-term care insurance, or to any employer of the consumer without the consumer's written consent.

(4) The Attorney General may bring an action in the name of the Commonwealth, or as parens patriae on behalf of consumers, to enforce this section. In any action brought by the Attorney General to enforce this section, a violation of this section is subject to a civil penalty of the following:

(a) Two thousand five hundred dollars ($2,500) for each violation of this section;

(b) The recovery of actual damages incurred by consumers on whose behalf the action was brought; and

(c) Costs and expenses incurred by the office of the Attorney General.

(5) The disclosure of genetic data pursuant to this section shall comply with all state and federal laws for the protection of privacy and security. This section shall not apply to protected health information that is collected by a covered entity or business associate governed by the privacy, security, and breach notification rules issued by the United States Department of Health and Human Services, 45 C.F.R. pts. 160 and 164, established pursuant to the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, and the federal Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5.

Effective: July 14, 2022

History: Created 2022 Ky. Acts ch. 169, sec. 1, effective July 14, 2022.

Legislative Research Commission Note (7/14/2022). 2022 Ky. Acts ch. 169, sec. 4, provides that this statute as created in Section 1 of that Act may be cited as the Genetic Information Privacy Act.